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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,718	01/03/2002	David S. Hungerford	21418-PA-DIV	4599

7590 08/12/2005  
ARMSTRONG, WESTERMAN & HATTORI, LLP  
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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b><i>Advisory Action Before the Filing of an Appeal Brief</i></b>	<b>Application No.</b> 10/039,718	<b>Applicant(s)</b> HUNGERFORD ET AL.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: None.  
 Claim(s) objected to: None.  
 Claim(s) rejected: 36-46 and 58-70.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
A 1.132 Declaration by Carmelita G. Frondoza asserts that introducing a DNA sequence into a chondrocyte as disclosed by Glorioso et al would result unpredictable phenotype and unpredictable growth pattern of the chondrocyte. However, this assertion of unpredictability is not supported by evidence. If this unpredictability was of any significance, it is believed it would have interfered with the use of transfected chondrocytes as disclosed by Glorioso et al, and Glorioso et al would have recognized this problem. However, Glorioso et al make no mention of any unpredictability as alleged. Any unpredictability from transfecting chondrocytes would have been of a minor nature that would not have been expected to prevent culturing the chondrocytes on a microcarrier in a spinner flask as suggested by Frondoza et al, Schinstine et al and Cherksey to obtain results of such culturing as suggested by these references. Frondoza et al, Schinstine et al and Cherksey are not non-analogous art as asserted by applicants since the references relate to culturing cells, which is required in Glorioso et al. The arguments concerning Starling et al are unpersuasive. Starling et al is not relied on for spinner culture, since this is suggested by the references applied as set forth above. There is seen no reason why a carbon dioxide atmosphere cannot be used when performing spinner culture with microcarriers. If the atmosphere is carbon dioxide, obviously essentially no oxygen will be present in the atmosphere.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

U.S. Patent and Trademark Office  
PTOL-303 (Rev. 4-05)

Advisory Action Before the Filing of an Appeal Brief

Part of Paper No. 20050809

Continuation of 5. Applicant's reply has overcome the following rejection(s): Rejections under 112 except for reciting "low" in claim 65.  
Rejection on double patenting over claims of 6,378,424 B1 or 6,662,805 B2.